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HEALTH-RELATED QUALITY OF LIFE AFTER RESTORATIVE PROCTOCOLECTOMY: A CROSS-SECTIONAL STUDY

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ABSTRACT

Background and Aims: **Patients undergoing restorative proctocolectomy have often suffered from active ulcerative colitis which should be remembered when assessing quality of life after operation. The aim of this study was to explore health-related quality of life after restorative proctocolectomy in those with poor or good pouch function and to compare that to patients with active or inactive ulcerative colitis and to the general population.**

Material and Methods: **Altogether, 282 restorative proctocolectomy patients were investigated. The control group comprised 408 ulcerative colitis patients from the local register. Generic 15D and disease-specific inflammatory bowel disease questionnaire health-related quality of life instruments were used. Population-based data were available for 15D. Pouch function was evaluated with Öresland score and colitis activity with simple clinical colitis activity index.**

Results: **15D results showed that patients with good pouch function had health-related quality of life similar to that of the general population. Health-related quality of life with inflammatory bowel disease questionnaire was equally good in patients with good pouch function (n = 131; 70%) and inactive colitis (n = 95; 63%), and equally impaired in patients with poor pouch function (n = 56; 30%) and active colitis (n = 18; 12%).**

Conclusion: **The majority of patients had health-related quality of life comparable to that in general population. Most patients with active ulcerative colitis are likely to improve their health-related quality of life after successful surgery. These findings are important when informing colitis patients about life after surgery.**

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Key words: Quality of life; restorative proctocolectomy; IPAA; ulcerative colitis; 15D instrument; inflammatory bowel disease questionnaire

INTRODUCTION

Restorative proctocolectomy (RPC) is the standard operation for patients with active ulcerative colitis (UC) (1). With successful surgery, patients can avoid a permanent stoma and are able to live a normal life. Health-related quality of life (HRQoL) is essential in evaluating the long-term results of the operation, since RPC may be associated with complications and functional failures (2, 3).

Many studies have shown that HRQoL in RPC patients has been comparable to that in general population (4–6). On the other hand, poor functional results are associated with impaired quality of life (7–9), which again may influence these patients' daily lives. It must be noted that patients undergoing RPC usually suffer from active colitis and HRQoL after the operation is important in this group.

Here, we compared results separately to non-operated colitis patients with active or inactive disease and similarly in RPC patients with good or poor functional result. This information about functional outcome and quality of life is valuable when the physician is discussing surgical treatment with the patient.

MATERIAL AND METHODS

PATIENT SELECTION

This cross-sectional study included all consecutive 352 patients with UC who underwent RPC at the Tampere University Hospital between 1985 and 2009; the subjects were identified in the hospital records using the International Classification of Diseases, 9th Revision (ICD-9) and International Classification of Diseases, 10th Revision (ICD-10) codes for UC and official codes for the operations performed. A database to form an RPC registry was collected from patient files including details on patient history, operation technique, postoperative morbidity, and follow-up. Of these, 282 had their pouch in function and could be located and they were sent questionnaires. Data were collected between October 2012 and May 2013. The control group consisted of 408 age- and sex-matched UC patients from the local inflammatory bowel disease (IBD) register. It is a prospective register for all adult patients with IBD. Cases were collected retrospectively before 1986 and after that prospectively. The age and gender distributions of the study group and the control group were similar. See the selection path for the groups in Fig. 1. The clinical data of the study patients are retrieved from these registries mentioned above.

QUESTIONNAIRES

The questionnaires were sent by mail, and one reminder was sent to the non-respondents. Two different instruments were used to measure HRQoL; one generic (15D) and one disease specific (inflammatory bowel disease questionnaire (IBDQ)). Pouch function was assessed by Öresland score (10) and disease activity in non-operated

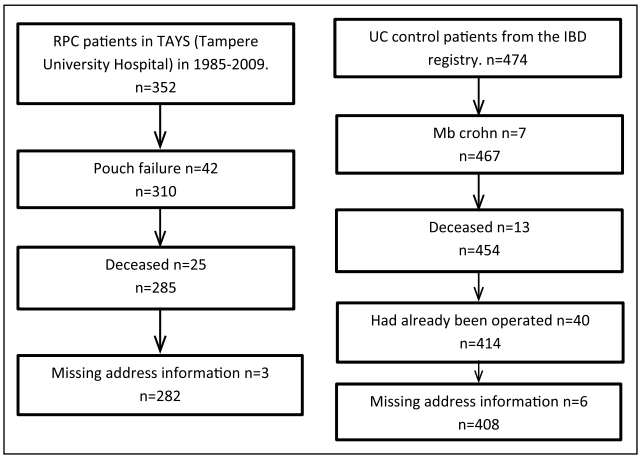

Fig. 1. Flow chart of the formation of the study and the control group.

subjects with UC by simple clinical colitis activity index (SCCAI) (11). The 15D instrument is Finnish, and the other questionnaires were translated from English into Finnish by official translators and a back-translation into English was done to confirm the linguistic accuracy of the translation.

The 15D is a generic self-administered measure of HRQoL. The instrument can be used both as a profile and as a single score measure. The questionnaire includes 15 dimensions: mobility, vision, hearing, breathing, sleeping, eating, speech, excretion, usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity. For each dimension, respondents choose one of the five ordinal levels best describing their current state of health. The valuation system is based on an application of multi-attribute utility theory. The single-index score (15D score), reflecting overall HRQoL on a 0–1 scale (1 = full health, 0 = being dead) and similarly, the dimension level values, reflecting the goodness of the levels relative to no problems on the dimension = 1 and to being dead = 0, were calculated from the questionnaire using a set of population-based preference or utility weights. Mean dimension level values were used to draw 15D profiles. A difference of ≥0.03 in 15D score was considered clinically important in the sense that a person can, on average, feel the difference (18). The 15D has been used with IBD patients before (12). The 15D data for general population came from the National Health 2011 Survey representing Finnish population aged 18 and above. This sample (n = 4763) was weighted to reflect the age and gender distribution of the patients (13).

A disease-specific IBDQ is a widely used standardized 32-item questionnaire, which addresses four different aspects of life: digestive symptoms, social functioning, emotional status, and systemic symptoms. The questionnaire has been validated in patients undergoing RPC for UC (14). It has been translated into Finnish and used in

TABLE 1
Characteristics of RPC and the control UC patients and also the non-respondents.

	Number of patients	Female, n (%)	Age at survey, years, median (range)	Time from diagnosis, years, median (range)	SCCAI, n (%)		
					≤2	3–4	≥5
Non-operated patients	153	71 (46)	55 (24–81)	20 (6–48)	95 (62)	39 (25)	18 (12)
Non-respondents	255	112 (44)	49 (25–79)	21 (6–48)			
				Time from operation	Öresland score, n (%)		
					<8	≥8	
RPC patients	187	87 (47)	53 (23–81)	13 (4–28)	131 (70)	56 (30)	
Non-respondents	95	43 (45)	48 (24–89)	12 (3–27)			

SCCAI: simple clinical colitis activity index; RPC: restorative proctocolectomy.

IBD (15). Total IBDQ score ranges from 32 to 224, a higher score indicating better quality of life.

Pouch function was assessed by Öresland score (10). It includes items about the number of daytime and night-time bowel movements, incontinence for liquid or solid stools, pad usage, urgency, diet, medication, and social handicap; these ratings are summarized into a single score (range, 0–15; 15 being worst). The questionnaire was translated into Finnish and was used with the permission of the developer (10). This questionnaire has been tailored for RPC and used in previous studies to elicit pouch function and HRQoL in UC. In the study by Berndtsson et al., poor Öresland scores correlated negatively with HRQoL results (7). The authors classified the score indicating very good 0–4, good 5–7, or poor pouch function 8–15. We decided to combine the groups with very good and good pouch function and hence the limit was set at a score of 8.

Disease activity of UC was measured using the SCCAI (11). A score of ≤2 was defined as remission, 3–4 as mild or moderately active disease, and ≥5 as severely active disease (16, 17).

STATISTICS

The data were analyzed using SPSS (IBM Corp, released 2012. IBM SPSS Statistics for Windows, version 21.0; IBM Corp, Armonk, NY).

The 15D index was chosen to be the main parameter with which the power calculations were made in the planning phase. With 15D difference ≥0.03 can be detected by an individual (18). Power calculations have been made using PS program difference being 0.03, power 80%, and statistical difference 0.05. In this way, both groups need to include 142 patients.

For categorical variables, the results are given as frequencies and percentages and for continuous variables as means and standard deviation or as medians. Comparisons between different patient groups were tested with chi-square test and in IBDQ scores with Kruskal–Wallis test. Independent samples *t*-test was used to compare the mean 15D scores of the patients and the age- and gender-standardized sample of general population. *P-values* ≤ 0.05 were considered statistically significant.

RESULTS

The gender distribution of the respondents was 47% of women in the study and 46% in the control group. The median age was 53 years in the study group and 55 years in the control group. The demographic data on both groups for responders and non-responders are shown in Table 1.

RPC PATIENTS

Of the 352 patients operated on between 1985 and 2009, pouch failure (pouch excision or permanent ileostomy without excision) had occurred in 42 and were excluded, 3 could not be reached and 25 had died (Fig. 1). Of the eligible 282 patients, 187 (66.3%) returned the questionnaires; 87 (67%, n = 130) of the women and 100 (66%, n = 152) of the men. The median age of the patients was 53 (range, 23–81) years, and the median follow-up time after RPC was 13 (range, 4–28) years.

The 95 RPC patients who did not return the questionnaire were on average three and a half years younger than those who did respond; there was no gender difference between respondents and non-respondents. When we compared the clinical data concerning the operation, we found that there was no significant difference in leakage or pelvic sepsis between the respondents and non-respondents.

Altogether, 131 (70%) of the patients had a well-functioning pouch with a score of <8, and 56 (30%) had a poor pouch function.

UC PATIENTS

In non-operated UC patients, 153 (37.5%) of 408 returned the questionnaire. Seventy-one (46%) of them were women and 82 (54%) men. The median age of the patients was 55 (range, 24–81) years. Of the non-operated UC patients 95 (62.1%) were in remission, 39 (25.5%) had mild to moderately active disease, and 18 (11.8%) severely active, as defined by SCCAI.

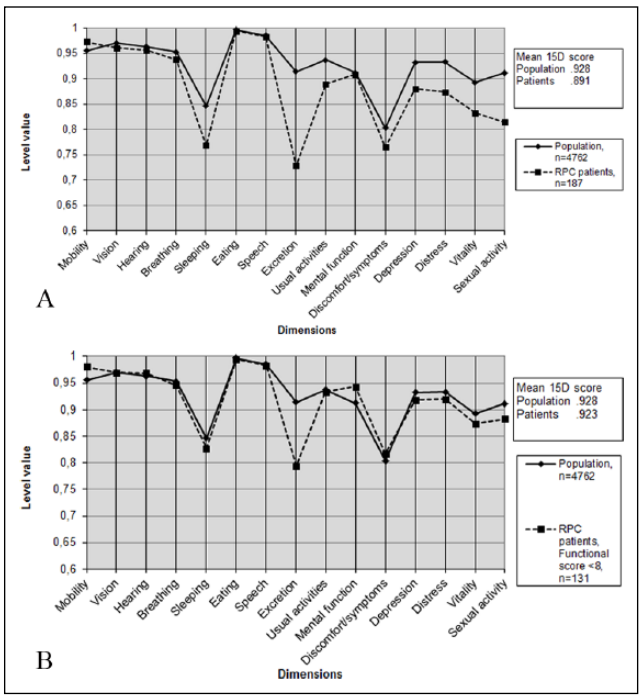

Fig. 2. (2A) 15D scores of all restorative proctocolectomy patients with ileal pouch (n = 187) compared to general population n = 4762 and (2B) scores for well-functioning pouches (n = 131) in comparison to the population.

15D SCORES

The mean 15D score of the RPC patients undergoing surgery was lower (0.891 (0.097)) than that of general population (0.928 (0.077); $p < 0.001$). The RPC patients scored statistically significantly lower on 8 of the 15 dimensions compared to the age- and gender-standardized sample of general population: sleeping, usual activities, excretion, discomfort and symptoms, depression, distress, vitality, and sexual activity (Fig. 2A). In RPC patients with well-functioning pouches, the only significantly decreased score was in excretion (Fig. 2B).

IBDQ SCORES

Fig. 2A shows that HRQoL was equally good in patients with good pouch function and inactive UC when measured by disease-specific IBDQ and also equally impaired in those with poor pouch function and active UC.

The IBDQ subscores for the different groups are presented in Table 2.

Patients with good pouch function showed better results in all subscores than those with active colitis ($p < 0.001$). There was no difference between groups when divided by the indication for surgery ($p = 0.135$–0.850).

The IBDQ scores for subgroups of different indications for patients undergoing surgery compared to UC of different disease activity are shown in Fig. 3B. Fig. 3C shows the IBDQ scores of operated patients with different time from operation.

There was no difference in HRQoL after surgery in different indications or time from operation. The scores were lower for RPC patients for any indication for surgery or time from operation than UC patients in remission but higher than UC patients with active disease.

DISCUSSION

This study investigated HRQoL using generic (15D) and disease-specific (IBDQ) questionnaires in a large cohort of patients operated on at a single institution within a period spanning over two decades. The main finding of this study was that RPC patients with a well-functioning pouch achieved HRQoL similar to that in general population and UC patients with their disease in remission or mild to moderate activity.

HRQoL has previously been reported to improve after RPC and reach the level of that in general population (4–6), although the results are inconsistent (19, 20). In a recent Finnish multicentre study HRQoL was impaired compared to the general population. This study also aimed to identify factors for poor outcome and found older age at time of operation and preoperative hypertension to be significant predictors (21). In this study, most (n = 131,70.1%) of the RPC patients had well-functioning pouch. Well-functioning pouch was associated with good HRQoL, and therefore, the majority of RPC patients were satisfied with their lives after surgery. Poor functional results of the pouch have been associated with low HRQoL (7–9, 22). This was also shown in this study. This is something about which we can inform the patients preoperatively even though we do not know the reliable risk factors to identify patients prone to poor pouch function or pouch failure before surgery (23, 24).

UC patients with only mildly active disease or the disease in remission reported quality of life equally as good as that of RPC patients with well-functioning pouch. The quality of life scores were equally poor in patients with poorly functioning pouch or severely active UC. An Italian study showed similar results: UC in remission showed an overall QoL similar to that of uncomplicated RPC patients, while the same two groups of patients with mild clinical activity had an overall QoL score similar to those of patients with complicated RPC (25). A recent study also showed that even though RPC patients reported higher bowel movement frequency than patients treated with anti-TNF (tumor necrosis factor), the RPC patients reported better outcomes for general HRQoL (26).

The patients who are considered for operative treatment are those with active acute severe colitis or medically refractory disease or those with dysplasia or cancer. There was no difference in HRQoL when comparing study patients divided by indication. But, as we can see in Fig. 3B, patients in remission undergoing surgery due to dysplasia or cancer were likely to experience deterioration in HRQoL, whereas patients operated on for active disease experience an improvement in HRQoL after successful surgery. For dysplasia patients, we should emphasize the fact that with surgical treatment potentially life-threatening disease

TABLE 2

IBDQ scores and subscores of patients undergoing surgery for different indications, pouch function groups, and control colitis patients for different disease activity groups.

Mean scores (MD)	Total score	Bowel disorder	Emotional function	Systemic symptoms	Social function
Patients undergoing surgery					
Indication					
Acute colitis (n = 79)	170.3 (36.8)	5.3 (1.0)	5.4 (1.3)	5.1 (1.3)	5.7 (1.4)
Medically refractory (n = 93)	165.9 (35.7)	5.0 (1.1)	5.3 (1.2)	4.6 (1.3)	5.9 (1.2)
Cancer or risk of cancer (n = 15)	172.3 (33.3)	5.3 (0.7)	5.3 (1.4)	4.8 (1.1)	6.4 (0.7)
Pouch function					
Good, score <8 (n = 131)	181.7 (27.1)	5.6 (0.7)	5.6 (1.0)	5.1 (1.1)	6.3 (0.9)
Poor, score ≥8 (n = 56)	136.1(34.2)	4.2 (1.0)	4.2 (1.2)	3.8 (1.2)	4.9 (1.5)
Colitis patients not undergoing surgery					
UC in remission (n = 95)	199.3 (16.8)	6.3 (0.6)	6.2 (0.6)	5.7 (0.8)	6.8 (0.4)
UC mildly active (n = 39)	173.4 (25.0)	5.4 (0.8)	5.4 (1.0)	4.7 (1.1)	6.2 (0.8)
Active UC (n = 18)	133.7 (38.3)	4.1 (1.3)	4.1 (1.2)	3.7 (1.3)	4.6 (1.6)

UC: ulcerative colitis.

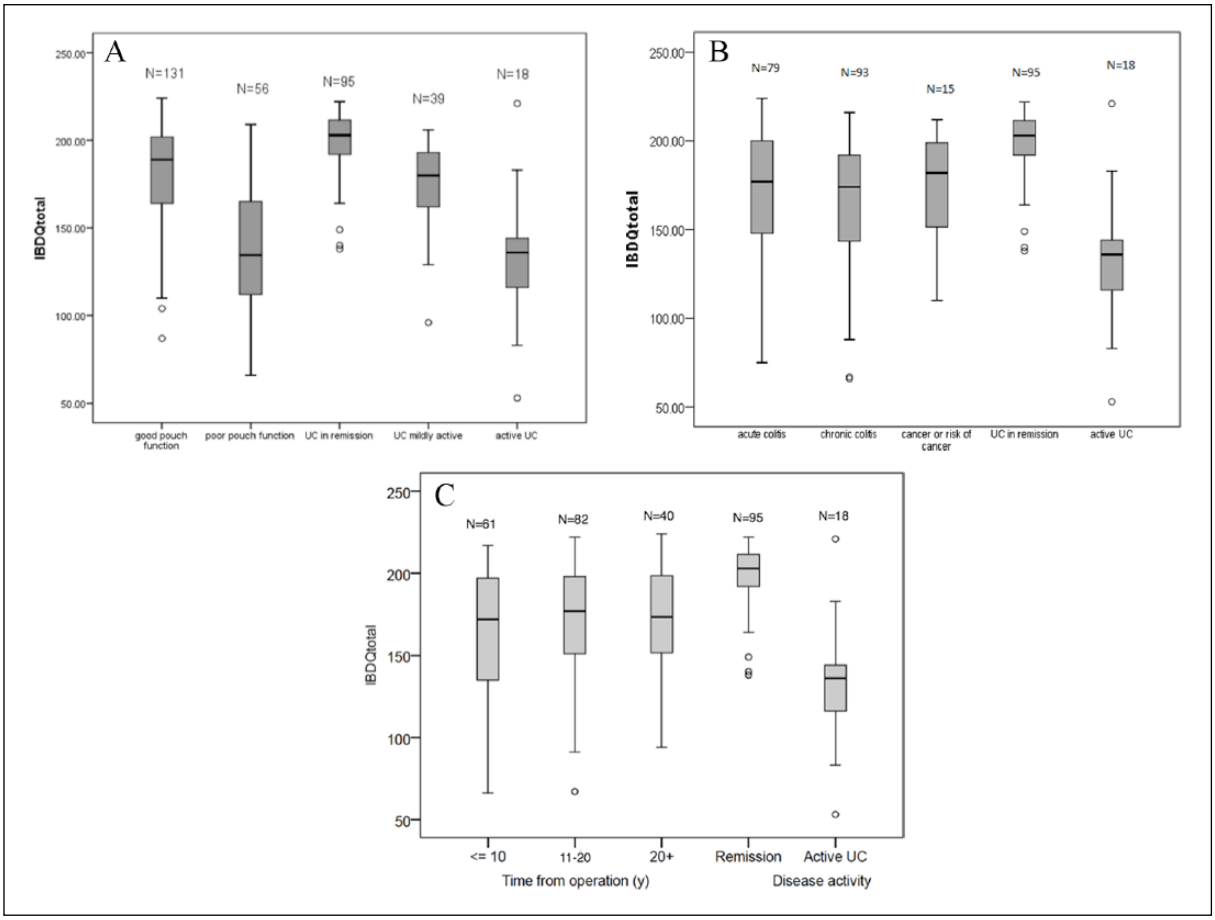

Fig. 3. IBDQ total scores in different subgroups of patients with ileal pouch or ulcerative colitis (UC) compared to non-operated patients for different disease activity groups. The score limits for each subgroup have been described in the Methods section; pouch function was measured by Öresland score and the activity of colitis by SCCAI score. (A) IBDQ total scores for good and poor functioning pouches. (B) IBDQ total scores in different subgroups of indication for surgery. (C) IBDQ total scores on subgroups on how much time had passed since operation.

will be treated, and yet, one can in most cases perform ileal pouch surgery with moderately good and stable HRQoL without permanent ileostomy.

The long-term results are important, since most of the patients undergoing surgery are young; the median follow-up time of 13 (range, 4–28) years in this study

gives a good perspective on this. Quality of life was not dependent on the time elapsing since the operation.

A limitation of this study was the large number of patients who did not return the questionnaires. Response rates have declined in Finland in recent decades both in men and women in all age groups, faster among men and in younger age groups (27). The non-response rate was high especially in non-operated UC. Nevertheless, it was possible make comparisons between patients with active and inactive UC, as we had enough patients in each activity group. Furthermore, there was no gender difference between operated and non-operated colitis patients, and the median age was almost the same. For comparison, in the entire colitis register, 45% were women, that is, the same percentage as in this study. The non-responders in RPC group were 3 years younger than the responders. Although younger patients have had slightly better functional results, we assume that this small difference did not influence the results significantly. Pelvic inflammatory complications may impair the functional outcome (28, 29). The respondents and non-respondents did not differ in leakage or pelvic sepsis. Therefore, we assume that the functional result that we used on dividing the RPC groups was valid. We did not investigate RPC patients who had experienced pouch failure. It would have not been possible to study the HRQoL before and after the pouch failure, which we think would have given the full picture. We did not include the patients undergoing permanent ileostomy. The number of such patients was low, including mostly elderly patients with a poor sphincter function and do not have RPC as an option. We did not have individual information about pre- and postoperative HRQoL. However, the results of our study show the same trend as studies with preoperative HRQoL data of how HRQoL improves after surgery (4, 6).

In conclusion, this study showed that successful RPC surgery for UC affords the majority of patients good and stable functional results. This again enables good long-term HRQoL, being comparable to that in the general population and in UC patients in remission. In the case of poor pouch function, quality of life remains at the same level to that in active UC. On the other hand, the surgery removes the disease-carrying colon, eliminating several risks, such as bleeding or cancer development, and in most patients, burdensome and expensive medications can be discontinued. Nevertheless, our results are important when counseling the patients before the operation.

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DECLARATION OF CONFLICTING INTERESTS

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

ETHICAL APPROVAL

The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki (6th revision, 2008). The Research and Ethics Committee of Pirkanmaa Hospital District approved the study (R12100). All participants gave written informed consent.

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